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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN R&D IRELAND,)
et al.,)
)
Plaintiffs,)
)
vs.) Civil Action No.
) 10-5954 (WHW) (MCA)
LUPIN LIMITED, et al.,)
)
Defendants.)

HIGHLY CONFIDENTIAL

The videotaped deposition of MICHAEL JOHN
ZAWOROTKO, Ph.D., called for examination, taken
pursuant to the Federal Rules of Civil Procedure
of the United States District Courts pertaining to
the taking of depositions, taken before JANET L.
ROBBINS, CSR No. 84-2207, Certified Shorthand
Reporter of the State of Illinois, at 6 West
Hubbard Street, Suite 500, Chicago, Illinois, on
October 11, 2013, at 9:03 a.m.

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1 Q. In general any API. 03:01:30

2 A. There are many, many, many, many 03:01:33

3 instances of hydrates and solvates forming from 03:01:35

4 impurities in the solution, many, many examples. 03:01:41

5 Q. Can you point me to a single example 03:01:45

6 showing that an ethanolate was formed based on the 03:01:48

7 presence of an ethanol stabilizer in methylene 03:01:51

8 chloride solution? 03:01:56

9 A. No, but there are many, many, many 03:01:58

10 examples of organic molecules forming solvates or 03:02:02

11 hydrates from very low concentrations of the 03:02:06

12 solvent or -- or water in the solution. 03:02:12

13 Q. Have you ever formed an ethanolate of 03:02:15

14 any API using methylene chloride to synthesis the 03:02:19

15 API? 03:02:26

16 A. I have used methylene chloride in 03:02:29

17 ethanol as a mixed solvent before consciously, but 03:02:31

18 I don't recall what the outcome of those 03:02:36

19 experiments was. 03:02:39

20 Q. My question is: Have you ever formed 03:02:39

21 an ethanolate of any API using methylene chloride 03:02:42

22 in the synthesis of that API? 03:02:51

23 A. No, not to my knowledge. 03:02:55

24 Q. Ghosh 1998 does not teach how to make 03:03:06

25 an ethanolate form of darunavir, correct? 03:03:12

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1 MS. RAGHAVAN: Objection to form, vague 03:03:17
2 as to the term "teach." 03:03:22
3 THE WITNESS: If teach -- if by teach 03:03:30
4 you mean provides enough information for a 03:03:46
5 person of ordinary skill in the art to get to 03:03:50
6 darunavir -- crystalline darunavir 03:03:55
7 monoethanolate, I believe that the Ghosh 1998 03:03:57
8 does, as I detail in my report. 03:04:01
9 BY MS. ROYZMAN: 03:04:04
10 Q. The question is: Does Ghosh 1998 03:04:04
11 provide any conditions for crystallizing 03:04:08
12 darunavir? 03:04:13
13 MS. RAGHAVAN: Objection to the form, 03:04:13
14 vague. 03:04:15
15 THE WITNESS: It does not provide any 03:04:22
16 specific conditions. But as I detail in my 03:04:28
17 report, I believe that it -- nevertheless, 03:04:30
18 that the -- or, I should say, that the 03:04:39
19 isolation of the solid form is obvious to a 03:04:41
20 person of skill in the art, the step of 03:04:44
21 isolation would be obvious to a person of 03:04:47
22 skill in the art. 03:04:51
23 MS. ROYZMAN: Let's go off the record 03:04:54
24 and take a break. 03:04:55
25 MS. RAGHAVAN: Okay. 03:04:56

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1	THE VIDEOGRAPHER: This is the end of	03:04:57
2	Media No. 3. We're going off the record.	03:05:02
3	The time is 3:03 p.m.	03:05:04
4	(A recess was had.)	03:24:22
5	THE VIDEOGRAPHER: This is the	03:24:22
6	beginning of Media No. 4. We are back on the	03:24:37
7	record. The time is 3:23 p.m.	03:24:40
8	Please proceed.	03:24:43
9	(Zaworotko Exhibit 13 was marked	09:27:54
10	for identification.)	03:24:43
11	BY MS. ROYZMAN:	03:24:43
12	Q. Dr. Zaworotko, let me hand you as	03:24:44
13	Exhibit No. 13 U.S. Patent 6,248,775, issued	03:24:46
14	June 19, 2001.	03:24:56
15	I believe you refer to this patent as	03:24:57
16	the '775 patent in your expert report and that we	03:24:59
17	have been talking about from time to time today.	03:25:04
18	MS. RAGHAVAN: This is 13?	03:25:08
19	THE WITNESS: Yeah, my lucky number.	03:25:12
20	MS. RAGHAVAN: Okay.	03:25:15
21	MR. REDDY: I think Ghosh '98 was	03:25:22
22	Exhibit 13, wasn't it?	03:25:24
23	THE WITNESS: No, it was 14 --	03:25:26
24	MR. REDDY: Oh.	
25	THE WITNESS: -- according to this.	03:25:27

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1 Q. Okay. So darunavir was patented as of 03:26:36
2 June 19, 2001, correct? 03:26:42
3 MR. REDDY: Objection to the extent it 03:26:49
4 seeks a legal conclusion and outside the 03:26:52
5 scope of his report. 03:26:54
6 THE WITNESS: The -- the date of the 03:26:59
7 issue of the patent was June 2001. I'm -- 03:27:09
8 I'm just curious about the priority date, 03:27:13
9 which is why I was looking in there, but 03:27:16
10 it's -- 03:27:18
11 BY MS. ROYZMAN: 03:27:18
12 Q. I can tell you what the priority date 03:27:18
13 is. The priority date is August 1994 -- 03:27:20
14 A. Yeah. So it's ahead -- 03:27:25
15 Q. -- for -- for darunavir.
16 A. Yeah, it's ahead of Ghosh '98. 03:27:27
17 Q. Yes. And so darunavir was patented 03:27:29
18 prior to the filing of your '613 patent which 03:27:40
19 lists a variety of anti-HIV compounds, correct? 03:27:46
20 MS. RAGHAVAN: Objection to the form. 03:27:53
21 THE WITNESS: I'll have to go back.
22 MS. RAGHAVAN: I think you're referring 03:28:00
23 to Zaworotko Exhibit 11, right? 03:28:01
24 MS. ROYZMAN: I believe so, yes. 03:28:05
25 MS. RAGHAVAN: Yeah. 03:28:08

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